SECTION 9

DATA ANALYSIS AND REPORTING

This section provides guidance on (1) analysis of laboratory data for both screening and intensive studies that should be included in State data reports and (2) data reporting requirements for a national database (National Fish Tissue Data Repository) for fish and shellfish contaminant monitoring programs.

All data analysis and reporting procedures should be documented fully as part of the Work/QA Project Plan for each study, prior to initiating the study (see Appendix E). All routine data analysis and reporting procedures should be described in standard operating procedures. In particular, the procedures to be used to determine if the concentration of a target analyte in fish or shellfish tissue differs significantly from the selected Screening Value (SV) must be clearly documented.

9.1 DATA ANALYSIS

9.1.1 Screening Studies

The primary objective of **Tier 1** screening studies is to assist States in identifying potentially contaminated harvest areas where further investigation of fish and shellfish contamination may be warranted. The criteria used to determine whether the measured target analyte concentration in a fish or shellfish tissue composite sample is different from the SV (greater than or less than) should be clearly documented. If a reported target analyte concentration exceeds the SV in the screening study, a State should initiate a **Tier 2**, **Phase I**, intensive study (see Section 6.1.2.1) to verify the level of contamination in the target species. Because of resource limitations, some States may choose to conduct a risk assessment using screening study data; however, this approach is not recommended because a valid statistical analysis cannot be performed on a single composite sample. If a reported analyte concentration is close to the SV but does not exceed the SV, the State should reexamine historic data on water, sediment, and fish tissue contamination at the site, and evaluate data on laboratory performance. If these data indicate that further examination of the site is warranted, the State should initiate a **Tier 2**, **Phase I**, intensive study to verify the magnitude of the contamination.

Because replicate composite samples are not required as part of a screening study, estimating the variability of the composite target analyte concentration at any site is precluded. The following procedure is recommended for use by

States for analysis of the individual target analyte concentration for each composite sample from reported laboratory data (see Section 8.3.3.3)

- A datum reported below the method detection limit (MDL), including a datum reported as not detected (i.e., ND, no observed response) should be assigned a value of one-half the MDL.

- A datum reported between the MDL and the method quantitation limit (MQL) should be assigned a value of the MDL plus one-half the difference between the MQL and the MDL.

- A datum reported at or above the MQL should be used as reported.

This approach is similar to that published in 40 CFR Parts 122, 123, 131, and 132—Proposed Water Quality Guidance for the Great Lakes System.

If resources permit and replicate composite samples are collected at a suspected site of contamination, then a State may conduct a statistical analysis of differences between the mean target analyte concentration and the SV, as described in Section 9.1.2.

9.1.2 Intensive Studies

The primary objectives of **Tier 2** intensive studies are to confirm the findings of the screening study by assessing the magnitude and geographic extent of the contamination in various size classes of selected target species. The EPA Office of Water recommends that States collect replicate composite samples of three size classes of each target species in the study area to verify whether the mean target analyte concentration of replicate composite samples for any size class exceeds the SV for any target analyte identified in the screening study. The statistical approach for this comparison is described in Section 6.1.2.7.

The following procedure is recommended for use by States in calculating the mean arithmetic target analyte concentration from reported laboratory data (see Section 8.3.3.3.3).

- Data reported below the MDL, including data reported as not detected (i.e., ND, no observed response) should be assigned a value of one-half the MDL.

- Data reported between the MDL and the MQL should be assigned a value of the MDL plus one-half the difference between the MQL and the MDL.

- Data reported at or above the MQL should be used as reported.

This approach is similar to that published in 40 CFR Parts 122, 123, 131, and 132—Proposed Water Quality Guidance for the Great Lakes System.

Secondary objectives that may be assessed as part of **Tier 2** intensive studies can include defining the geographical region where fish contaminant concentrations exceed screening values (SVs); identifying geographical distribution of contaminant concentrations; and, in conjunction with historical data or future data collection, assessing changes in fish contaminant concentrations over time. The statistical considerations involved in comparing fish contaminant levels measured at different locations or times are discussed in Appendix M.

State staff should consult a statistician in interpreting intensive study tissue residue results to determine the need for additional monitoring, risk assessment, and issuance of a fish or shellfish consumption advisory. Additional information on risk assessment, risk management, and risk communication procedures will be provided in later volumes in this guidance series.

9.2 DATA REPORTING

9.2.1 State Data Reports

State data reports should be prepared by the fish contaminant monitoring program manager responsible for designing the screening and intensive studies. Summaries of **Tier 1** screening study data should be prepared for each target species sampled at each screening site. For **Tier 2** intensive studies (**Phase I** and **Phase II**), data reports should be prepared for each target species (by size class, as appropriate) at each sampling site within the waterbody under investigation (see Section 6.1.2). Screening and intensive study data reports should include, at a minimum, the information shown in Figure 9-2.

9.2.2 Reports to the National Fish Tissue Data Repository

The EPA Office of Science and Technology within the Office of Water has established a NFTDR. The NFTDR is a collection of fish and shellfish contaminant monitoring data gathered by various Federal, State, and local agencies. The objectives of the NFTDR are to:

- Facilitate the exchange of fish and shellfish contaminant monitoring data nationally by improving the comparability and integrity of the data
- Encourage greater cooperation among regional and State fish advisory programs
- Assist States in their data collection efforts by providing ongoing technical assistance.

The NFTDR is currently part of the EPA's Ocean Discharge Evaluation System (ODES) database, a primary source for maintaining, retrieving, and analyzing freshwater, estuarine, and marine data. The EPA Office of Water selected the ODES database to serve as a national repository for fish and shellfish contaminant monitoring data for both inland and coastal waters. Unfortunately,

- Study identification (e.g., project number, title, and study type)
- Program manager
- Sampling site name
- Latitude (in degrees, minutes, and seconds)
- Longitude (in degrees, minutes, and seconds)
- Type of waterbody (lake, river, estuary, etc.)
- Name of waterbody
- Sampling date (e.g., DD, MM, YY)
- Sampling time (e.g., HH, MM in a 24-h format)
- Sampling gear type used (e.g., dredge, seine, trawl)
- Sampling depth
- Scientific name of target species
- Common name of target species
- Composite sample numbers
- Number of individuals in each composite sample
- Number of replicate composite samples
- Predominant characteristics of specimens used in each composite sample
  - Predominant life stage of individuals in composite
  - Predominant sex of individuals in composite (if applicable)
  - Average age of individuals in composite (if applicable)
  - Average body length or size (mm)
  - Description of edible portion (tissue type)

(continued)

Figure 9-1. Recommended data reporting requirements for screening and intensive studies.

- Analytical methods used (including method for lipid analysis)
- Method detection and quantitation limits for each target analyte
- Sample cleanup procedures (e.g., additional steps taken to further purify the sample extracts or digestates)
- Data qualifiers (e.g., additional qualifying information about the measurement)
- Percent lipid (wet weight basis) in each composite sample
- For each target analyte in each composite sample:
  - Total wet weight of composite sample (g) used in analysis
  - Measured concentration (wet weight basis) as reported by the laboratory (see Section 8.3.3.3.3)
  - Units of measurement for target analyte concentration
  - Evaluation of laboratory performance (i.e., description of all QA and QC samples associated with the sample(s) and results of all QA and QC analyses)
- In screening studies with only one composite sample for each target species, the State should provide for each target analyte a comparison of reported concentration with selected SV and indication of whether SV was exceeded (see Section 9.1.1).
- In intensive studies, for each target analyte in each set of replicate composite samples, the State should provide
  - Range of target analyte concentrations for each set of replicate composite samples
  - Mean (arithmetic) target analyte concentration for each set of replicate composite samples (see Section 9.1.2)
  - Standard deviation of mean target analyte concentration
  - Comparison of target analyte arithmetic mean concentration with selected SV and indication of whether SV was exceeded.

Figure 9-1 (continued)

ODES has not evolved into a widely used database and there is relatively little fish and shellfish contaminant monitoring data currently stored in the NFTDR. To make this database more accessible, EPA intends to modify the existing NFTDR and incorporate it as a major prototype during the modernization (Phase III) of the STORET database. During prototype development, EPA will use actual fish contaminant monitoring data in ODES to identify needed data fields, to test the data structure, and to develop the necessary data analysis programs in the STORET database. During 1996, EPA intends to completely convert the NFTDR to a STORET-based fish contaminant monitoring database. The primary benefit of including the NFTDR as a subset of STORET is that one platform will be able to store both water quality data and biological data, such as fish and shellfish contaminant monitoring data. Existing data sets would be able to easily migrate to the new STORET system when it is completed in 1997.

State, regional, and local agency staff may obtain more information by writing to

National Fish Tissue Data Repository
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460